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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/499,423	07/07/1995	CAREY V. CAMPBELL	MP/84	2478

7590

01/15/2003

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/499,423

Applicant(s)

Campbell et al.

Examiner

Brian Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 11, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-33, 35, 42-44, 46-69, 71-77, 79-88, and 91-97 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-33, 35, 42-44, 46-69, 71-77, 79-88, and 91-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claim Objections

1. Claims 58-69 are objected to because of the following informalities: these claims ultimately depend from a canceled claim (45). Claim 58 should be amended to depend from a pending claim. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1,3-5,24-33,35,42-44,46-69,71,72,79-85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a tube with a layer of PTFE film, does not reasonably provide enablement for a tube itself that limits expansion beyond the second circumference. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. On page 6, lines 29-32 of Applicant's specification an explanation of how the second circumference is limited as a result of a layer of PTFE film. There is no mention of just the tube being capable of having an elastic limit, but only with the application of a layer of PTFE film.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear if applicant is intending to recite that the tube is a liner within another tubular structure or the tube has a liner in it. For example, claim 29 recites the "blood conduits are living blood vessels," which if interpreted that the liner is within another tube this implies a blood vessel forms part of the graft. This would be non-statutory subject matter.

Claim Rejections - 35 U.S.C. § 102

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1,3-5,24-31,33,35,86-88,91,95-97 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldfarb (6436135). Goldfarb discloses a tube of PTFE (col. 3, lines 40-55) that is fully capable of having its circumference increase with blood pressure application. The prosthesis is for use as a vascular graft, col. 1, lines 3-5. The graft is fully capable of being "adapted for" used as an endoluminal graft. The tube has a wall thickness about 0.25mm, col. 7, lines 9, 10. Regarding claim 4, the use of "about" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited, since it is not clear if about is ± 0.01 or ± 1 . Goldfarb also discloses the tubular graft is tapered between the

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first and second opposing ends, col. 7, lines 45-54. Regarding claim 91, the examiner asserts that the claimed physical properties (in this case, recoil) are present in the prior art material to some extent even though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art.

7. Claims 1,3-17,19-31,33,35,42-44,46-69, 71-77,79-88,91-97 are rejected under 35 U.S.C. 102(e) as being anticipated by Shannon et al. (5641373). Shannon et al. disclose a tube base made of porous PTFE and is covered by one or more layers of porous PTFE material, col. 2, lines 21-24. Shannon also discloses the device has a microstructure of nodes and fibrils, col. 1, lines 19-30. The wall thickness has about 0.1mm, see col.4, lines 51-53. The graft can be anchored via a stent, col. 11, lines 8-14 and also sutured, line 55. Regarding claims 17 and 31, since the graft is inherently capable of expanding to a second circumference, it is fully capable of having a tapered profile upon expansion in a tapered vessel. The limitation recited in claim 1, of applying internal pressure up to a second circumference such that the tube "limits further growth in the second circumference to remain substantially unchanged" or in claim 33, "limits further growth to *substantially* the second circumference" fails to distinguish the expansion beyond the second circumference as being different from the first to second circumferential expansion.

Therefore, the claim language reads on a further expansion up to the second circumference. With respect to claims 10-13,42-44,46-69, 71-77,79-88,91-94, the examiner asserts that the claimed physical properties (in this case, recoil) are present in the prior art material to some extent even though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to

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show that these properties are not present in the prior art. Shannon does disclose that the enlargement of the graft is at least permitted to 5% upon a force exerted on the tube, col. 8, lines 51-54. It would be inherent that the graft is also capable of recoiling which would be the same percentage as what the graft was permitted to expand at. This falls within the claimed range of minimal recoil of 7% or less.

8. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon et al. '899 in view of Hughes et al. (4728328). Shannon et al. is explained supra. However, Shannon does not disclose a tube that is branched with three ends. Hughes et al. teach a tubular prosthesis that is branched with three ends, Fig. 12. It would have been obvious to one of ordinary skill in the art to use the branched tubular form as taught by Hughes with the prosthesis of Shannon in a vessel such as the trachea requiring replacement to the two bronchi.

9. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldfarb '135 in view of Hughes et al. (4728328). Goldfarb is explained supra. However, Goldfarb does not disclose a tube that is branched with three ends. Hughes et al. teach a tubular prosthesis that is branched with three ends, Fig. 12. It would have been obvious to one of ordinary skill in the art to use the branched tubular form as taught by Hughes with the prosthesis of Goldfarb in a vessel such as the trachea requiring replacement to the two bronchi.

10. Claims 42-44, 46-50, 52-56, 58-62, 64-68, 71-77, 79-85, 92-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldfarb '135. Goldfarb is explained supra. However, Goldfarb does not disclose the tube having minimum recoil at 14% or less. It would have been

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obvious matter of design choice to modify the tubular graft of Goldfarb and have the minimal recoil at 14% or less, since applicant has not disclosed that having the recoil percentage provides an advantage, solves any stated problem or is for any particular purpose. One of ordinary skill, furthermore, would have expected Applicant's invention to perform equally well with any recoil of the Goldfarb tube or the claimed 14% or less since both perform the same function as permitting blood flow through without bursting. With respect to claims 50,56,62,68 the use of suture to secure the graft is well known in the art. Regarding claims 47,59,65, the use of a catheter to apply force to distend the graft is well known in the art.

Response to Arguments

11. Applicant's arguments filed 10/11/02 have been fully considered but they are not persuasive. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. Regarding the Shannon reference, the graft has a second circumference that remains "substantially unchanged" or does not "grow beyond" the second circumference since it has sintered reinforcement tape wrapped about the outer circumference to prevent breaking, col. 2, lines 21-25. It should be noted that the recoil limitation was in dependent claims which the Examiner was addressing, except for claim 42.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for this group is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceedings should be directed to the group receptionist whose telephone number is (703) 308-0858.



Brian E. Pellegrino

January 9, 2003



Paul Prebilic
Primary Examiner
TC 3700, AU 3738